

**REMARKS**

Claims 1-26 were pending in the application. Claim 1 has been amended. Accordingly, upon entry of this amendment, claims 1-26 will be pending.

Support for the amendment to claim 1 may be found throughout the specification, including the originally filed claims.

*No new matter has been added.* Any amendments to and/or cancellation of the claims was done solely to more particularly point out and distinctly claim the subject matter of Applicants' invention in order to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

**RESPONSE TO RESTRICTION REQUIREMENT**

The Examiner has required restriction to one of the following inventions under 35 U.S.C. § 121:

- Group I: Claims 1-6, 14-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig alpha-1, classified in class 435, subclass dig 2;
- Group II: Claims 1-5, 7, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig alpha-2, classified in class 435, subclass dig 2;
- Group III: Claims 1-5, 8, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig epsilon, classified in class 435, subclass dig 2;
- Group IV: Claims 1-5, 9, 13-16, 18, 19-21, 22 and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-1, classified in class 435, subclass dig 2;
- Group V: Claims 1-5, 10, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-2, classified in class 435, subclass dig 2;
- Group VI: Claims 1-5, 11, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-3, classified in class 435, subclass dig 2;
- Group VII: Claims 1-5, 12, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-4, classified in class 435, subclass dig 2;
- Group VIII: Claim 17, drawn to a method of screening for candidate agents comprising administering at least two separate probes, classified in class 435, subclass dig 2;
- Group IX: Claim 24, drawn to a method of quantifying the amount of germline constructs, classified in class 435, subclass 4;

- Group X: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Igα1 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XI: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Igα2 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XII: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig epsilon, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XIII: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-1, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XIV: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-2, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XV: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-3, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;
- Group XVI: Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-4, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810;

It is the position of the Examiner that Groups I-VII are unrelated because they are “not disclosed as capable of use together and have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01).” The Examiner further states that the inventions of Groups I-VII are “drawn to using materially distinct probes directed to distinct targets, e.g., Ig alpha-2, Ig-epsilon, Ig gamma-2, etc.”

Applicants provisionally elect **Group III, with traverse**, for prosecution on the merits. Applicants’ grounds for traversal are set forth below.

Applicants traverse the restriction requirement to the extent that groups I-VII should be reformed as a single group containing claims 1-23 (referred to hereinafter as “**newly formed Group I**”). Applicants’ grounds for traversal are set forth below.

It is respectfully submitted that Applicants have presented an allowable generic claim, claim 1, which is generic to the claims set forth in groups I-VII proposed by the Examiner. Claim 1, as amended, is drawn to methods of screening for candidate agents capable of

modulating germline transcription, comprising: adding a library of candidate agents to a plurality of cells; preparing mRNA from said plurality of cells to form an mRNA mixture; adding to said mixture at *least a first RNase protection probe (RPP) substantially complementary to a first germline mRNA from an immunoglobulin heavy chain gene locus* to form a first hybridization complex between said first germline mRNA and said first RPP; adding an RNase protection enzyme (RPE) to said mixture, such that mRNA that is not protected is digested; quantifying the amount of said first germline mRNA as compared to a cell in the absence of a candidate agent; and identifying at least one candidate agent that alters the amount of said first germline mRNA.

It is Applicants' position that given the presence of claim 1, which is generic to groups I-VII proposed by the Examiner, a restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect *newly formed Group I*, claims 1-23.

It is Applicants' position that while a species election may be proper among groups I and VII for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim (see M.P.E.P. §809.02). Claim 1 embraces the species of RNase protection probes (RPPs) which are complementary to germline mRNAs from an immunoglobulin heavy chain gene locus. If a species election is required, Applicants further provisionally elect Group III for search purposes only. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

Applicants are further requested to elect a single species for each of the following: claim 18, drawn to small molecules, claims 19-21, drawn to peptides, and claims 22 and 23, drawn to retroviruses.

Applicants respectfully traverse the species election. Applicants respectfully submit that a search for the claimed method for screening for a candidate agent capable of modulating germline transcription comprising adding a library of candidate agents to a plurality of cells will necessarily include any library of candidate agents, and therefore will be co-extensive.

However, to be considered responsive to the instant Restriction Requirement, Applicants elect under 35 U.S.C. §121, with traverse, *claim 18, small molecules*, as the species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1 and 18 are readable on this species. It is Applicants'

Application No.: 09/847,960  
Amendment and Response dated August 4, 2003  
Reply to Restriction Requirement dated July 2, 2003

Group Art Unit: 1639

understanding that the search will be extended to the remaining species upon a finding of allowability.

Applicants believe no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. RGV-0012 from which the undersigned is authorized to draw. A duplicate of this sheet is enclosed.

Dated: August 4, 2003

Respectfully submitted,

By

  
Lisa M. DiRocco, Esq.

Registration No.: 51,619

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney for Applicants